

REMARKS

The Office Action of August 7, 2003, has been received and reviewed. Claims 1, 3-9, 11, 13-19 and 29-34 are pending in the application. All claims stand rejected. Claims 1, 3, 8, 9, 11, 14, 17-19, 29 and 33 have been amended, and claims 4-7, 13 and 34 have been canceled as set forth herein. All amendments and cancellations are made without prejudice or disclaimer. Reconsideration is respectfully requested.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 3-9, 11, 13-19 and 29-34

Claims 1, 3-9, 11, 13-19 and 29-34 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claims 4-7, 13 and 34 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as set forth herein.

Specifically, it was thought that the phrase “endogenous SsgA” was unclear. As known in the art, the term “endogenous” refers to being produced or originating within a cell and the term “SsgA” refers to the product of the *ssgA* gene. The phrase “endogenous SsgA,” thus, refers to the product of the *ssgA* gene in the cell. Accordingly, one of ordinary skill in the art would understand that the phrase “Streptomyces or Saccharopolyspora bacterium lacking detectable endogenous SsgA” of amended claim 1 means that the Streptomyces or Saccharopolyspora bacterium does not produce SsgA by itself. Thus, amended independent claim 1 should be definite. Independent claims 30 and 33 including the phrase “endogenous SsgA” should also be definite.

The phrase “providing.....with the capability of having or expressing heterologous SsgA” was also thought to be unclear. Applicants note that independent claims 30 and 33 do not include this phrase and that the rejection should not apply to any of claims 30-34.

With regard to amended claim 1, it recites in part “providing a Streptomyces or a Saccharopolyspora bacterium, said Streptomyces or a Saccharopolyspora bacterium lacking detectable endogenous SsgA, with an expressible polynucleotide encoding a heterologous SsgA

comprising the sequence of SEQ ID NO: 3.” As amended, it should be clear that the Streptomyces or a Saccharopolyspora bacterium of claim 1 is provided with “an expressible polynucleotide encoding a heterologous SsgA comprising the sequence of SEQ ID NO: 3.” Thus, amended claim 1 should be definite.

Accordingly, reconsideration and withdrawal of the indefiniteness rejections of claims 1, 3, 8-9, 11, 14-19 and 29-33 are requested.

Claims 1, 3-9, 11, 13-19, and 29

Claims 1, 3-9, 11, 13-19, and 29 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Claims 4-7 and 13 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejection as set forth herein.

Specifically, it was thought that the term “gene” was unclear. Although applicants do not agree that any of the claims are indefinite, to expedite prosecution, the term “gene” has been replaced with the term “polynucleotide” in claim 1 in accordance with the Examiner’s suggestion.

Reconsideration and withdrawal of the indefiniteness rejections of claims 1, 3, 8-9, 11, 14-19 and 29 are requested.

Claims 5-7

Claims 5-7 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Claims 5-7 have been canceled rendering the rejections thereof moot.

Claims 30-32

Claims 30-32 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. Applicants respectfully traverse the rejections as set forth herein.

Specifically, it was thought that the phrase “means for enhancing” was thought to be unclear. Independent claim 30 recites in part “a means for enhancing septation and

fragmentation” and should be construed as a means-plus-function element in accordance with 35 U.S.C. § 112, sixth paragraph. As stated by the Federal Circuit “the PTO may not disregard the structure disclosed in the specification corresponding to such language when rendering a patentability determination.” (M.P.E.P. § 2181 *quoting In re Donaldson Co.*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994)). Thus, “the USPTO must apply 35 U.S.C. 112, sixth paragraph in appropriate cases, and give claims their broadest reasonable interpretation, in light of and consistent with the written description of the invention in the application.” (*Id.*). When the phrase “means for enhancing septation and fragmentation” is read in light of the specification, one of ordinary skill in the art would understand the structure that is claimed. (*See, Specification* as-filed, page 3, line 33 through page 4, line 29).

Reconsideration and withdrawal of the indefiniteness rejections of claims 30-32 are requested.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement

Claims 1, 3-9, 11, 13-19, 29 and 33

Claims 1, 3-9, 11, 13-19, 29 and 33 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement for a method for rendering any or all filamentous actinomycete bacteria to exhibit reduced branching and fragment septation and enhanced fragmentation. Claims 4-7 and 13 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as set forth herein.

Although applicants do not agree that the specification does not enable independent claim 1 or 33, to expedite prosecution, claims 1 and 33 have been amended as set forth herein. Amended independent claim 1 is directed to “providing a *Streptomyces* or *Saccharopolyspora* bacterium ... with an expressible polynucleotide encoding a heterologous SsgA comprising the sequence of SEQ ID NO: 3.” Since the as-filed specification discloses working examples of producing recombinant *Streptomyces* and *Saccharopolyspora* bacteria, amended claim 1 is enabled. (*See, Specification* as-filed, page 15, line 13 through page 16, line 4; *see also Id.* at page 16, line 31 through page 17, line 21).

Turning to independent claim 33, it has been amended to recite in part “wherein the Actinomycete bacterium is selected from the group consisting of *Streptomyces coelicolor*, *Streptomyces lividans*, *Streptomyces clavuligerus* and *Saccharopolyspora erythraea*.” Since the as-filed specification discloses a working example of the production of recombinant bacteria for each of the listed bacteria, claim 33 is enabled. (*See, Id.*).

Reconsideration and withdrawal of the enablement rejections of claims 1, 3, 8-9, 11, 14-19, 29 and 33 are requested.

Claims 1, 3-9, 11 and 13-19

Claims 1, 3-9, 11 and 13-19 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement for a method of transforming or transfecting a filamentous bacteria with any DNA comprising ssgA gene, a derivative or fragment thereof. Claims 4-7 and 13 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as hereinafter set forth.

Specifically, it was thought that claims 1, 3-9, 11 and 13-19 are “so broad as to encompass any DNA with ssgA activity isolated from any source or derived from any source including derivatives, variants, mutants and recombinants.” (Office Action, page 9). Although applicants do not agree that any of the claims lack enablement, to expedite prosecution, independent claim 1 has been amended to recite in part “an expressible polynucleotide encoding a heterologous SsgA comprising the sequence of SEQ ID NO: 3.” As amended, independent claim 1 is not directed to any DNA, but is directed to a nucleotide encoding SsgA comprising SEQ ID NO: 3 and, thus, should be enabled. (*See, Specification* as-filed, page 3, line 33 through page 4, line 21 and Sequence Listing).

Reconsideration and withdrawal of the enablement rejections of claims 1, 3, 8-9 and 13-19 are requested.

Written Description

Claims 1, 3-9, 11 and 13-19 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors has possession of the claimed invention. Claims 4-7 and 13 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections as set forth herein.

It was thought that the specification does not contain “any disclosure of the structure of all such polynucleotides or genes comprising SsgA DNA sequences.” (Office Action, page 11). Although applicants do not agree that any of the claims lack compliance with the written description requirement, independent claim 1 has been amended to recite in part “an expressible polynucleotide encoding a heterologous SsgA comprising the sequence of SEQ ID NO: 3.” Since SEQ ID NO: 3 is the protein sequence, *e.g.*, SsgA, encoded by a polynucleotide, the specification conveys to one of ordinary skill in the art that the applicants had possession of claim 1. (*See*, Specification as-filed, page 3, line 33, through page 4, line 21; *see also* Sequence Listing, SEQ ID NOS: 1 and 3).

Accordingly, reconsideration and withdrawal of the written description rejections of claims 1, 3, 8-9, 11 and 14-19 are requested.

Rejections under 35 U.S.C. § 102

Claims 1, 3-9, 11, 13-15 and 29-34 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Kawamoto et al. Claims 4-7, 13 and 34 have been canceled rendering the rejections thereof moot. Applicants respectfully traverse the rejections.

Kawamoto et al. cannot anticipate any of independent claims 1, 30 or 33 since Kawamoto et al. does not disclose each and every element of any of the independent claims. With regard to claim 1, the Office Action states “Kawamoto et al. disclose a strain of *Streptomyces* NRRL B2682 which sporulates in liquid medium but produces profuse branches and does not sporulate in rich medium. Kawamoto et al. disclose that the very same bacterium forms septum only after transformation with *ssgA*. It is clear from this information that such a strain was not producing detectable levels of SsgA endogenously before transformation, because if detectable levels of

SsgA was being produced by said strain, it would have formed septum and not spores or filaments.” (Office Action, at pages 13-14).

However, *Streptomyces* NRRL B2682 **does** produce detectable levels of endogenous SsgA. As illustrated in Fig. 2(a), (b) and (c) of Kawamoto et al., strain B2682 of *S. griseus*, before being transformed with a plasmid encoding SsgA, **does** produce detectable levels of SsgA. (See, Kawamoto et al., page 1081, Fig. 2). Fig. 2 depicts, in panels (a), (b) and (c), Western blots having bands that indicate the production of SsgA. (See, *Id.*). Further, since it is known that wild-type *S. griseus* B2682 produces spores in many types of media and that sporulation correlates with SsgA accumulation, the *S. griseus* of Kawamoto et al. has detectable levels of SsgA. (See, *Id.* at page 1077 and Abstract). Thus, Kawamoto et al. cannot anticipate amended claim 1.

Each of independent claim 30 and amended independent claim 33 also recites in part “lacking a detectable endogenous SsgA” and as established herein, Kawamoto et al. discloses that strain B2682 of *S. griseus* does produce endogenous SsgA. Each of claim 30 and amended claim 33 also recites “wherein the Actinomycete bacterium is selected from the group consisting of *Streptomyces coelicolor*, *Streptomyces lividans*, *Streptomyces clavuligerus* and *Saccharopolyspora erythraea*.” Kawamoto et al. does not disclose any of *Streptomyces coelicolor*, *Streptomyces lividans*, *Streptomyces clavuligerus* and *Saccharopolyspora erythraea*, but rather discloses *S. griseus*. (See, *Id.* at page 1079, Table 1). Accordingly, Kawamoto et al. cannot anticipate claim 30 or amended claim 33.

Reconsideration and withdrawal of the anticipation rejections of claims 1, 3, 8-9, 11, 14-15 and 29-33 are, thus, requested.

Rejections under 35 U.S.C. § 103

Claims 16-19 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Kawamoto et al. as applied to claims 1, 3-9, 11, 13-15 and 29-34 above, and further in view of the common knowledge in the art for making recombinant heterologous proteins. Applicants respectfully traverse the rejections.

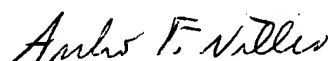
Claims 16-19 are nonobvious, at the very least, as depending from nonobvious independent claim 1. (*See, In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)).

Thus, reconsideration and withdrawal of the obviousness rejections of claims 16-19 are requested.

CONCLUSION

In view of the amendments and remarks presented herein, applicants respectfully submit that the amended claims define patentable subject matter. If questions should remain after consideration of the foregoing, the Examiner is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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